1.3.1. SOUTH AFRICAN PACKAGE INSERT

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SCHEDULING STATUS: **S2**

PROPRIETARY NAME: **PYNSTOP®**

(AND DOSAGE FORM) **(TABLET)**

COMPOSITION:

Each tablet contains:

Codeine phosphate	10 mg
Doxylamine succinate	5 mg
Paracetamol	450 mg
Caffeine	45 mg

Sugar free

Excipients: Colour Lake blend PB-21082 green, Gelatine, Maize starch, Magnesium stearate, Purified talc, Sodium starch glycolate.

PHARMACOLOGICAL CLASSIFICATION:

A 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:

PYNSTOP tablets have analgesic, antipyretic and antihistaminic properties.

INDICATIONS:

PYNSTOP tablets for adults are indicated for the symptomatic relief of mild to moderate pain and pain associated with tension and fever.

CONTRAINDICATIONS:

PYNSTOP tablets are contraindicated in:

Sensitivity (allergy) to the active ingredients.

Severe liver function impairment.

Respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion.

During an attack of bronchial asthma.

Heart failure secondary to lung disease.

Head injuries and conditions in which intracranial pressure is raised.

The presence of acute alcoholism.

After operations on the biliary tract.

WARNINGS AND SPECIAL PRECAUTIONS:

Codeine: Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependence and addiction.

Codeine should be given with extreme caution to patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.

Caffeine to be used with care by patients with a history of peptic ulceration.

Large doses may precipitate fits in epileptics. Use with care in conditions such as glaucoma and prostatic hypertrophy.

Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

Consult a doctor if no relief is obtained from the recommended dosage.

Do not use continuously for more than 10 days without consulting your doctor.

Dosages in excess of those recommended may cause severe liver damage.

PYNSTOP tablets should not be given to children under 12 years of age.

Patients suffering from liver or kidney disease should only take paracetamol under medical supervision.

INTERACTIONS:

This medicine may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants.

Doxylamine succinate may enhance the sedative effect of central nervous system depressants including

alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives.

PREGNANCY AND LACTATION:

Safety of **PYNSTOP** in pregnant and lactating women has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years: One or two tablets repeated four hourly if necessary. Do not exceed eight tablets per day. Consult your doctor if no relief is obtained with the recommended dosage.

Do not exceed the stated dose.

SIDE EFFECTS:

Paracetamol:

Side effects of paracetamol are usually mild though haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis have been reported. Pancreatitis, skin rashes and other allergic reactions occur occasionally. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions.

Doxylamine succinate:

Sedation may occur. Other side effects include gastrointestinal disturbances, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest, and tingling, heaviness and weakness of the hands may occur. Symptoms of stimulation include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Codeine phosphate:

May cause nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, dizziness, slow pulse rate, low blood pressure when standing erect, subnormal body temperature, restlessness and changes of mood.

Caffeine:

Can cause the following side effects: nausea, headache, sleeplessness, irritability and symptoms of anxiety. Large doses may cause restlessness, excitement, muscle tremor, ringing of the ears, increased pulse rate and gastric ulceration.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Paracetamol:

In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison control centre must be contacted immediately.

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported. Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver injury may become manifest on the second day, (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Cerebral oedema and non-specific myocardial depression have also occurred.

In the event of overdosage consult your doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible.

Prompt treatment is essential. Any patient who has ingested 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered IV as soon as possible.

Acetylcysteine:

Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdosage.

IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses.

Acetylcysteine is effective if administered within 8 hours of overdosage.

Doxylamine succinate, codeine phosphate and caffeine:

Refer to '**SIDE-EFFECTS**'. Treatment is symptomatic and supportive.

IDENTIFICATION:

Green, circular, flat tablet with score line on one side and a diameter of 12,7 mm.

PRESENTATION:

18, 20, 40, and 100 tablets in PVC/Aluminium foil blister packs. White polypropylene securitainers with white LDPE (low density polyethylene) closures containing 50 and 100 tablets. White HDPE (high density polyethylene) containers with white HDPE screw-on closures containing 100 tablets. All pack sizes may not be marketed simultaneously.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC.

Do not remove the blister pack from the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

C/2.8/233

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

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